K020658

MAR 7 2002

EXHIBIT #1
5 pages

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

   Viatronix Inc.
   25 East Loop Road
   Suite 204
   Stony Brook, NY 11790
   Establishment Registration # 2438935
   Contact: Mr. Baman Pattanayak, Director of QA/RA

   Date Summary Prepared:

   January 7, 2002

2. **Name of the Device:**

   Viatronix V3D Colon, revision 1.1

3. **Predicate Device Information:**

   a. G. E. Navigator, 510(k) # K954355. This system is an add-on to the Advantage Windows Workstation. Many features in the manual reference the base workstation manuals. Therefore, some of the following references are to the Advantage Windows Manuals. (892.1000, Product Code: LNH)

   b. Siemens Realtime 3D Diagnostic Workstation, 510(k) # K973010. The trade name of this device is 3D Virtuoso. (892.2050, Product Code: 90LLZ)

c. Voxar VC Model 1.0, 510(k) # K012072. The trade name of this device is Voxar Colonscreen. (892.2050, Product Code: 90LLZ)

d. Vital Images Vitrea 2, Version 2.1, 510(k) # K002519. (892.2050, Product Code: 90LLZ)

e. Viatronix Visualization System, 510(k) # K002780. This system name is sometimes abbreviated as VVS. (892.2050, Product Code: 90LLZ)

4. **Device Description:**

The Viatronix V3D Colon contains all of the required hardware and software components to provide interactive 3D and 2D views of diagnostic CT and MR scan images of the colon. The views include both inner and outer surface 3D volume rendered images as well as orthogonal and multiplaner reformatted 2D images. This ability to view the dataset in different perspectives from which it was acquired is performed by first transferring DICOM images from the MR or CT scanners to the Viatronix V3D Colon, which automatically identifies regions of interest and displays these regions to the user in the above mentioned views. The user can then navigate freely within the dataset/region of interest or follow automatically computed paths to fly through the colon or around the outside of the colon structure. Measurements of the size of colon polyps, masses or lesions can be made for patient screening and for planning treatment.

5. **Intended Use:**

The Viatronix V3D Colon is a system for the display and visualization of 3D and 2D medical image data of the colon derived from DICOM 3.0 compliant CT and MR scans, for the purpose of patient screening and detection of polyps, masses, cancers and other lesions. It provides functionality for display, measurement and electronic cleansing to assure complete visualization of the colon from rectum to cecum and vice versa for both prone and supine views. It generates a centerline for guided interactive navigation and fly through of the entire colon, and also includes a reporting facility to enhance workflow for patient screening. It is intended for use by Radiologists, Clinicians and referring Physicians to process, render, review, archive, print and distribute colon image studies utilizing PC hardware.

6. **Comparison to Predicate Devices:**

The Viatronix V3D Colon Module (V3D Colon) utilizes the same technological characteristics as the five predicate devices. All provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. All provide measurement tools for analysis of the observed structures, allow adjustment to virtual lighting parameters to emphasize

details, and provide window/level adjustment of the 2D Views to enhance features.

V3D Colon and all five predicates, provide external 3D views. Only G.E. Navigator, 3D Virtuoso, Vitrea 2, and VVS provide endoluminal 3D views. As with Vitrea 2, Voxar VC, and VVS, the V3D Colon Module utilizes direct volume rendering for all of its 3D views, including transparent volume images and visible surface views. While 3D Virtuoso provides volume rendered images, in some cases there is initial surface extraction. G.E. Navigator utilizes surface extraction techniques for all 3D views. For changing the mapping to opacity during translucent views, V3D Colon is similar to Siemens 3D Virtuoso, Voxar VC, Vitrea 2, and VVS devices because all use the same technique of volume rendering.

With V3D Colon, the user may choose between automatic path planning or interactive flight control. The G.E. Navigator also automatically plans a path, but requires the user to build the path in many short segments by pressing a button for each step. In essence, the V3D Colon Module performs the Navigator "auto step and align" function multiple times until the end of the organ is found. Vital Images Vitrea 2 allows the user to move forward by dragging the mouse forward keeping the viewpoint within the hollow of the organ by bouncing off the walls. VVS and V3D Colon also restrict the view to the hollow of the organ by bouncing off the walls in a similar way.

Siemens 3D Virtuoso performs semi-automatic segmentation by calculating each step of the segmentation process, allowing the user to view the results and then interactively adjust any incorrect features. The V3D Colon Module is similar, but performs the complete segmentation before requiring the user to interact with the system to adjust the results.

G.E. Navigator, Voxar VC, VVS, and V3D Colon are specifically designed to streamline the typical colon examination. They provide the ability to load both supine and prone datasets at the same time. They also allow the setting of landmarks (points of interest), reviewing these in an organized fashion, and the entering of comments specific to each landmark.

We conclude that the subject device, the Viatronix V3D Colon, is as safe and effective as its predicate devices and poses no new questions of safety and effectiveness.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:**

Testing was conducted using phantoms with structures of a known size and distance from the start inserted into the phantom. The person using the system did not have advance knowledge as to the number of structures nor their size and

location. An independent reviewer then compared the test results with the actual phantoms and made an assessment as to accuracy.

The Viatronix V3D Colon has been developed in a manner consistent with accepted standards for software development, including test protocols. Testing on phantom objects has determined its level of accuracy, which is substantially equivalent to that of its predicate devices. The product has shown itself to be reliable, easy to use and capable of rendering useful 3D medical images.

8. Discussion of Clinical Tests\Evaluations Performed:

Clinical tests on patients were done to verify that the system performs as intended with a broad sampling of input data. Each patient was assessed as to whether the core functionality of the Viatronix V3D Colon permitted fly through and visualization. Comparisons were made with optical endoscopy to give a qualitative judgment as to its ability to visualize structures. Comparisons to its predicate devices were also made as to its quality and effectiveness.

The Clinical data was reviewed by a radiologist who determined that the rendering was accurate and medically useful. The radiologist was experienced with the predicate devices and found it substantially equivalent in essential features with improvements in the speed of rendering and the ease of performing segmentation.

9. Conclusions:

We conclude from these tests that the Viatronix V3D Colon is substantially equivalent to its predicate devices in its ability to render 3D images for use in medical diagnostics. In comparison to optical endoscopy, the Viatronix V3D Colon is able to visualize structures of similar size and shape.

Attached as Exhibit # 5 is our "Clinical Test Plan" which details tests performed, includes sample test forms, includes completed test forms (raw data) and outlines apparatus employed for optical endoscopy, with the following documents attached:

- System Clinical Test Results (Phantom Studies)
- System Clinical Test Results (Visualization of Polyps)
- System Clinical Test Results (Human Studies)

Clinical studies were performed under IRB (Institutional Review Board) overview, which included Patient Consent Forms, in accordance with 12 CFR Part 52.

This document is included in Exhibit # 5.

In summary, we conclude that we met our goals of clinical testing as follows:

- Verified that an accurate 3D model of the entire colon is generated
- Verified that fly through in the 3D model of the entire colon is possible
- Verified that viewing 2D and MPR images of the entire colon is possible
- Using a phantom, verified that measurements are accurate
- Demonstrated the ability to fly through and visualize the entire colon
- Demonstrated the ability to visualize and measure polyps, masses and lesions for patient screening

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2002

Mr. Baman Pattanayak
Director of Quality and Regulatory Affairs
Viatronix Incorporated
25 East Loop Road
Suite 203
STONYBROOK NY 11790

Re: K020658
Trade/Device Name: Viatronix V3D Colon
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 28, 2002
Received: March 1, 2002

Dear Mr. Pattanayak:

This letter corrects our substantially equivalent letter of March 7, 2002 regarding the Viatronix V3D Colon. There was an ambiguity in the phrase "patient screening" in the Indications for Use, in that it could be taken to mean either screening a single patient's colon or screening a population of patients. The corrected Indications for Use removes the ambiguity by using instead the phrase "screening a colon."

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K020658/A

Device Name: Viatronix V3D Colon

Indications For Use:

The Viatronix V3D Colon is a system for the display and visualization of 3D and 2D medical image data of the colon derived from DICOM 3.0 compliant CT and MR scans, for the purpose of screening a colon to detect polyps, masses, cancers and other lesions. It provides functionality for display, measurement and electronic cleansing to assure complete visualization of the colon from rectum to cecum and vice versa for both prone and supine views. It generates a centerline for guided interactive navigation and fly through of the entire colon, and also includes a reporting facility to enhance workflow for screening a colon. It is intended for use by Radiologists, Clinicians and referring Physicians to process, render, review, archive, print and distribute colon image studies utilizing PC hardware.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Eyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020658

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)